

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and  
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC. and  
BAXTER HEALTHCARE CORPORATION,

Defendants.

Civil Action No.: 05-349-GMS

Jury Trial Demanded

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BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and  
BAYER HEALTHCARE LLC,

Counterdefendants.

**PUBLIC VERSION**

**BAXTER'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS'  
MOTION *IN LIMINE* NO. 1 TO PRECLUDE BAXTER FROM PRESENTING  
TESTIMONY REGARDING "DESIGN AROUNDS"**

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## I. INTRODUCTION

Plaintiffs resort to hyperbolic and false assertions of "ambush" in their attempt to preclude Baxter's damages expert, Bruce Den Uyl, from testifying about Baxter's design-around option – an option that cripples Plaintiffs' damages case. Further, Plaintiffs misapply the standard for proper expert testimony under Rule 702 by repeatedly arguing for exclusion of allegedly "unreliable" facts. Rule 702, however, concerns "sufficient facts" and "reliable principles and methods" for an expert opinion. Fed. R. Evid 702. More than ample facts in the record support Mr. Den Uyl's opinion, and the methodology he followed is standard and reliable. Thus, Plaintiffs' motion to exclude evidence of Baxter's design-around option should be denied.

## II. PLAINTIFFS HAVE NOT BEEN "AMBUSHED"

Plaintiffs claim that they have been "ambushed" by Mr. Den Uyl's reliance on facts obtained from Dr. Richard Schiff, who, Plaintiffs contend, was never "identified as an individual with relevant knowledge in this case." (Motion at 1, 3.) Plaintiffs are wrong on many levels.

*First*, Plaintiffs falsely state that Dr. Schiff was "the *sole* source of [Mr. Den Uyl's design-around] opinion." (Motion at 1 (emphasis added).) Yet, as evidenced in Mr. Den Uyl's expert report and deposition testimony, he relied on *many* sources for his design-around opinion, including: Dr. Schiff (Baxter's Global Dir. of Immune Therapy and Clinical Affairs), Angela Blackshere (Baxter's Global Dir. of Regulatory Affairs), Paul Estrem (Baxter's Vice President of Finance) and Dr. Terence Snape (Baxter's non-infringement expert). (See Rogaski Opp. Decl., Ex. 1 (Den Uyl Report) at 20-21; Ex. 2 (Den Uyl Dep.) at 122, 146-47.)

*Second*, contrary to their claims, Plaintiffs were well aware during fact discovery that Dr. Schiff had relevant knowledge in this case. Dr. Schiff was repeatedly referred to in at least three fact depositions of Baxter employees – e.g., Matt Fazio, Christophe Carnewal and Jennifer

Bergstrom. (Rogaski Opp. Decl., Ex. 3 (Fazio Dep.) at 14-15, 119, 146-47, 178-79, 181-82; Exh. 4 (Carnewal Dep.) at 343-34, 344-45; Ex. 5 (Bergstrom Dep.) at 7-8.) For example, Matt Fazio – only the second witness Plaintiffs deposed in this case – brought up Dr. Schiff's name *five* separate times in response to Plaintiffs' questions regarding Baxter personnel knowledgeable about clinical trials for the accused product, Gammagard® Liquid. (Rogaski Opp. Decl., Ex. 3 (Fazio Dep.) at 14-15, 119, 146-47, 178-79, 181-82.) Moreover, Dr. Schiff's name appears in dozens of documents in *both* parties' document production, including at least four deposition exhibits (LLOYD 3, LLOYD 36, BXTR 32, and BXTR 33). Thus, it is wholly disingenuous for Talecris to feign ignorance or feel "ambushed" about factual information provided by Dr. Schiff. Plaintiffs had every opportunity to depose Dr. Schiff, but chose not to. To the extent Plaintiffs claim prejudice by not deposing Dr. Schiff, they have only themselves to blame.

*Third*, Plaintiffs' complaint about Dr. Schiff not being identified in Baxter's initial or supplemental disclosures is hypocritical. On page 5 of his opening report (Rogaski Opp. Decl., Ex. 6), Talecris' damages expert, Christopher Bokhart, identifies *five* Talecris employees who provided relevant "information" to Mr. Bokhart for his affirmative report; however, *none* of these five individuals appeared on Plaintiffs' initial or supplemental disclosures. (Rogaski Opp. Decl., Exs. 7-8.) And only one of these five witnesses (Mary Kuhn) was disclosed in Talecris' discovery responses before the close of fact discovery. As the maxim goes, "a party seeking equity must do equity." *People's Nat'l Bank of Lynchburg v. Marye*, 191 U.S. 272, 286 (1903).

*Fourth*, it is worth emphasizing Mr. Den Uyl's role as a rebuttal expert. It was, after all, Mr. Bokhart who opined in his opening damages report that REDACTED

(Rogaski Opp. Decl., Ex. 6 at 35.) To rebut that opinion, Mr. Den Uyl spoke with Dr. Schiff (among others) regarding a design-around option available to Baxter. It is well-established that witnesses called for rebuttal need not be identified in advance. *See, e.g., FINAL*

PRETRIAL ORDER, rev. 3/29/07, at 2 n.4 ("Any witness not listed will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary, without prior notice to the opposing party.") There was, therefore, nothing impermissible about Mr. Den Uyl's reliance on Dr. Schiff as part of a *rebuttal* opinion regarding Baxter's design-around option.

In sum, Plaintiffs' "ambush" claim under Rule 37(c)(1) is wrong and certainly does not warrant the "extreme sanction" of exclusion. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 237 F.R.D. 106, 110 (D. Del. 2006) ("The exclusion of critical evidence under Rule 37(c)(1) is an extreme sanction, not imposed absent a showing of willful deception and flagrant disregard of a court order by the proponent of the evidence.").

### **III. THERE IS NOTHING UNRELIABLE ABOUT MR. DEN UYL'S TESTIMONY**

Throughout their motion, Plaintiffs mistakenly attack the reliability of the "facts" upon which Mr. Den Uyl based his testimony. For example, Plaintiffs refer to a supposed lack of "reliable evidence," "reliable factual basis," and reliable "factual support." (Motion at 1, 4, 5.) Plaintiffs, however, misapply Federal Rule of Evidence 702, which states that expert testimony must be based only on "sufficient facts" and "reliable principles and methods." Fed. R. Evid. 702; *see also* Fed. R. Evid. 702 advisory committee's note, 2000 Amendments; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993). The "reliability" prong, thus, refers to the principles and methods employed by the expert, not the underlying facts. It is for the jury to decide if facts were reliably proven. Plaintiffs have not proven that Mr. Den Uyl's "principles and methods" were unreliable, so denial of their motion is warranted.

Moreover, Mr. Den Uyl clearly followed the established and prevailing guidelines under the relevant test – as announced by the Federal Circuit in *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341 (Fed. Cir. 1999) and its progeny – in analyzing the availability and

acceptability of Baxter's design-around option. Consistent with *Grain Processing*, Mr. Den Uyl considered, among other things: the immediate availability of the necessary materials, equipment, know-how and experience to implement the design-around; the length of time to design, develop and gain FDA approval for the design-around; and the cost of bringing the design-around to the market – all supported by substantial facts and data. (Rogaski Opp. Decl., Ex. 1 at 20-21; Ex. 2 at 19-35, 142-47.) Further, he talked to all of the appropriate individuals,<sup>1</sup> considered all the relevant information, and correctly applied all the facts made known to him.<sup>2</sup> (*Id.*) Mr. Den Uyl's methodology is reliable and beyond reproach. If there is an issue concerning the reliability or sufficiency of the *facts* underpinning his opinion, "it is a matter affecting the weight and credibility of the testimony – a question to be resolved by the jury." *Inline Connection Corp. v. AOL Time Warner Inc.*, 470 F. Supp. 2d 435, 439 (D. Del. 2007).

#### IV. DR. SNAPE DOES NOT "CONTRADICT" MR. DEN UYL'S TESTIMONY

Plaintiffs distort the record, once again, with respect to an alleged inconsistency between Mr. Den Uyl and one of Baxter's technical experts, Dr. Terence Snape. Plaintiffs falsely claim that Dr. Snape "testified that the alleged design-around was not feasible." (Motion at 4.) That was *not* Dr. Snape's testimony. Instead, when asked in the abstract about Baxter's removal of steps from Baxter's accused process (which contains three viral inactivation or reduction steps),

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<sup>1</sup> As Plaintiffs know, Dr. Schiff was among the Baxter personnel with whom Mr. Den Uyl spoke about the design-around option. As Baxter's Global Director of Immune Therapy and Clinical Affairs and a member of the clinical trial team that tested the accused product, Dr. Schiff is a highly credible source for Mr. Den Uyl to rely upon regarding: (1) the acceptability of a design-around that  
 REDACTED and (2) the availability of this alternative process.

<sup>2</sup> Plaintiffs grossly mischaracterize the record when they cite a litany of items that Mr. Den Uyl supposedly did not consider or was unable to testify to. (Motion at 2-3.) Even a cursory review of the relevant deposition pages and expert report clearly demonstrates Mr. Den Uyl did his due diligence and followed established principles. (Rogaski Opp. Decl., Ex. 1 at 19-21; Ex. 2 at 19-35, 142-47.)

Dr. Snape testified

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(Rogaski Opp. Decl. at 151:14-152:18.)

There is no contradiction between Dr. Snape's testimony and Mr. Den Uyl's analysis of Baxter's design-around option since Mr. Den Uyl fully considers the cost and time of the FDA approval process. Specifically, Mr. Den Uyl opines that FDA approval for Baxter's design-around would take approximately

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depending on how significant the FDA considered the modification and whether clinical trials would be required. (Rogaski Opp. Decl, Ex. 1 at 21; Ex. 2 at 146-47.) To the extent there is a perceived inconsistency between Baxter's experts – and there is not – the proper vehicle to address this is through cross-examination, not exclusion. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

## V. CONCLUSION

For the foregoing reasons, Plaintiffs' motion *in limine* No. 1 should be denied.

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**CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on May 14, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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